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10/575,025	04/25/2007	Erick Carreira	0115-061069	7045

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EXAMINER
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HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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01/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,025	<b>Applicant(s)</b> CARREIRA ET AL.	
	<b>Examiner</b> Michael C. Henry	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/02/07</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-16 are pending in application

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1 recites the phrase "a straight-chain or branched lower alkyl group  $-(CH_2)_p-$ ". However, the claim is indefinite since it is unclear how a branched lower alkyl group can be represented by the formula  $-(CH_2)_p-$ . Claim 1 recites the phrase "a straight-chain or branched

lower alkyl group  $-(CH_2)_q-$ ". However, the claim is indefinite since it is unclear how a branched lower alkyl group can be represented by the formula  $-(CH_2)_q$ ".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

- (1) field of the invention
- (2) breath of the claims, and
- (3) possession of the claimed invention at the time of filing for each claimed

species/genus based upon the teachings of the specification and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claim is drawn to a method for the treatment or prevention of arteriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a compound according to claim 1. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicant claims a method for the prevention of arteriosclerosis comprising administering to a subject in need of such treatment an effective amount of a compound according to claim 1, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the prevention of such disease or condition does not have a single recognized cause. In fact, the aforementioned disease, is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) high blood pressure (2) high cholesterol (3) family history of heart disease or stroke (4) obesity (5) diabetes (6) sedentary life and lack of physical activity. These are only a few of the factors that promote these diseases in people. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the

said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said disease to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by preventing said disease. Similarly, claims 14 and 15 which are drawn to a pharmaceutical composition for preventing arteriosclerosis are also rejected since said composition cannot prevent said arteriosclerosis, as set forth above.

***Claim Rejections - 35 USC § 102***

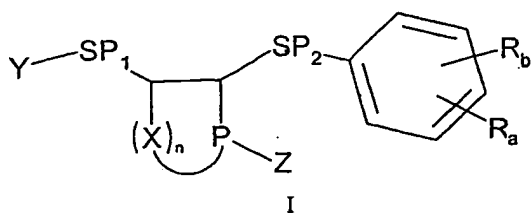
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Heek et al. (Journal of Pharmacology and Experimental Therapeutics (1997), 283 (1), pages 157-163) (Abstract Only).

In claim 1, applicant claims a compound according to formula I



wherein .....

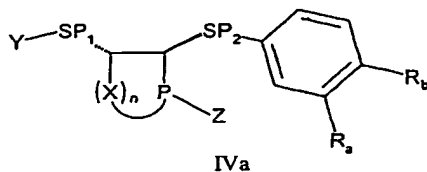
Van Heek et al. disclose applicant compound of formula I wherein P represents  $-\text{N}^<$ , X represents  $-\text{CH}_2-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b$  represents the formula  $-\text{Sp}_3-\text{R}_6$  wherein  $\text{Sp}_3$  represents  $-\text{O}-$  and  $R_6$  represents the carbohydrate structure A, Z represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$ ,  $\text{Sp}_2$  represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 2 is drawn to a compound according to claim 1, with the proviso, that if P =  $-\text{N}^<$ ,  $n=1$ , X =  $-\text{CO}-$  and  $\text{Sp}_2$  represents a covalent bond,  $R_b$  may not represent H or OH and  $\text{Sp}_3$  may not represent at a covalent bond,  $-\text{O}-$  or  $-\text{OCH}_2-$ . Van Heek et al. disclose applicant compound of formula I wherein P represents  $-\text{N}^<$ , X represents  $-\text{CH}_2-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b$  represents the formula  $-\text{Sp}_3-\text{R}_6$  wherein  $\text{Sp}_3$  represents  $-\text{O}-$  and  $R_6$  represents the carbohydrate structure A, Z represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$ ,  $\text{Sp}_2$  represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 3 is drawn to a compound according to claim 1, wherein P =  $-\text{N}^<$ ,  $n = 1$  and X =  $-\text{CO}-$ ,  $-\text{CS}-$ ,  $-\text{CH}_2-$  or  $-\text{NH}-$ . Van Heek et al. disclose applicant compound of formula I wherein P represents  $-\text{N}^<$ ,  $n = 1$ , and X represents  $-\text{CH}_2-$  (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 4 is drawn to a compound according to claim 1, wherein P =  $-\text{N}^<$ ,  $n = 1$  and X =  $-\text{CS}-$ ,  $-\text{CH}_2-$  or  $-\text{NH}-$ . Van Heek et al. disclose applicant compound of formula I wherein P represents  $-\text{N}^<$ ,  $n = 1$ , and X represents  $-\text{CH}_2-$  (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

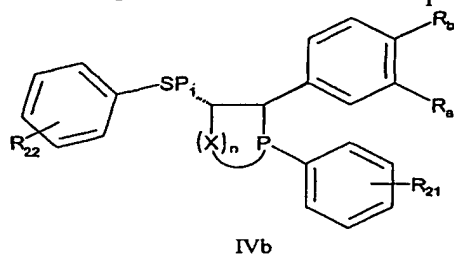
Claim 7 is drawn to a compound according to claim 1, having the formula IVa



wherein  $R_a$ ,  $R_b$ ,  $SP_1$ ,  $SP_2$ ,  $P$ ,  $X$ ,  $Y$ ,  $Z$  and  $n$  are as defined in claim 1.

Van Heek et al. disclose applicant compound of formula I wherein  $P$  represents  $-\text{N}<$ ,  $X$  represents  $-\text{CH}_2-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b$  represents the formula  $-\text{Sp}_3-\text{R}_6$  wherein  $\text{Sp}_3$  represents  $-\text{O}-$  and  $\text{R}_6$  represents the carbohydrate structure A,  $Z$  represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$ ,  $\text{Sp}_2$  represents a covalent bond and  $Y$  represents an aryl (a phenyl) (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 8 is drawn to compound according to claim 1 having the formula IVb,



wherein  $R_a$ ,  $R_b$ ,  $SP_1$ ,  $P$ ,  $X$  and  $n$  are as defined hereinabove and wherein  $R_{21}$  and  $R_{22}$  represent H, lower alkyl, lower alkoxy or halogen. Van Heek et al. disclose applicant compound of formula IVb wherein  $P$  represents  $-\text{N}<$ ,  $X$  represents  $-\text{CH}_2-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b$  represents the formula  $-\text{Sp}_3-\text{R}_6$  wherein  $\text{Sp}_3$  represents  $-\text{O}-$  and  $\text{R}_6$  represents the carbohydrate structure A,  $Z$  represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$ ,  $\text{Sp}_2$  represents a covalent bond,  $Y$  represents an aryl (a phenyl),  $R_{21}$  represents lower



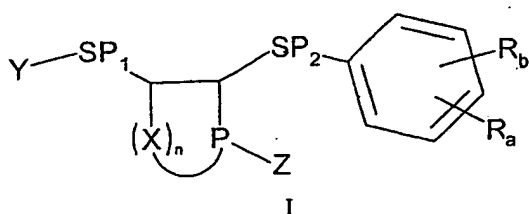
alkoxy and  $R_{22}$  represent H (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 9 is drawn to a compound according to claim 7, wherein  $P = -N<$ ,  $n = 1$  and  $X = -CO-$ ,  $-CS-$ ,  $-CH_2-$  or  $-NH-$ . Van Heek et al. disclose applicant compound of formula IVa wherein P represents  $-N<$ ,  $n = 1$ , and X represents  $-CH_2-$  (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claim 10 is drawn to a compound according to claim 7, wherein  $P = -N<$ ,  $n = 1$  and  $X = -CS-$ ,  $-CH_2-$  or  $-NH-$ . Van Heek et al. disclose applicant compound of formula IVa wherein P represents  $-N<$ ,  $n = 1$ , and X represents  $-CH_2-$  (see abstract). Van Heek et al.'s compound has a cas# = 198561-85-2 (see abstract).

Claims 1, 3, 7-9, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenblum et al. (Journal of Medicinal Chemistry (1998) 41, pages 973-980).

In claim 1, applicant claims a compound according to formula I



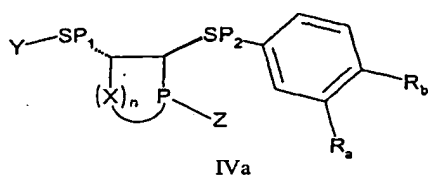
wherein .....

Rosenblum et al. disclose applicant's compound of formula I wherein P represents  $-N<$ , X represents  $-CO-$ ,  $n = 1$ ,  $R_a = H$ ,  $R_b = OH$ , Z represents a substituted aryl (a substituted phenyl),  $Sp_1$  represents a spacer unit  $-(CH_2)_p-$  wherein  $p = 3$  and is substituted with

OH,  $Sp_2$  represents a covalent bond and Y represents a substituted aryl (a substituted phenyl) (see page 974, compound 1, SCH 58235).

Claim 3 is drawn to a compound according to claim 1, wherein  $P = -N<$ ,  $n = 1$  and  $X = -CO-$ ,  $-CS-$ ,  $-CH_2-$  or  $-NH-$ . Rosenblum et al. disclose applicant compound of formula I wherein P represents  $-N<$ ,  $n = 1$ , and X represents  $-CO-$  (see abstract).

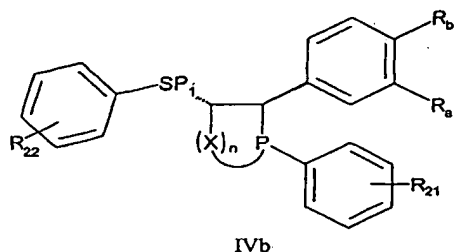
Claim 7 is drawn to a compound according to claim 1, having the formula IVa



wherein R<sub>a</sub>, R<sub>b</sub>, Sp<sub>1</sub>, Sp<sub>2</sub>, P, X, Y, Z and n are as defined in claim 1.

Rosenblum et al. disclose applicant's compound of formula IVa wherein P represents  $-N<$ , X represents  $-CO-$ ,  $n = 1$ , R<sub>a</sub> = H, R<sub>b</sub> = OH, Z represents a substituted aryl (a substituted phenyl), Sp<sub>1</sub> represents a spacer unit  $-(CH_2)_p-$  wherein  $p = 3$  and is substituted with OH, Sp<sub>2</sub> represents a covalent bond and Y represents a substituted aryl (a substituted phenyl) (see page 974, compound 1, SCH 58235).

Claim 8 is drawn to compound according to claim 1 having the formula IVb,



wherein R<sub>a</sub>, R<sub>b</sub>, Sp<sub>1</sub>, P, X and n are as defined hereinabove and wherein R<sub>21</sub> and R<sub>22</sub> represent

H, lower alkyl, lower alkoxy or halogen. Rosenblum et al. disclose applicant's compound of formula IVb wherein P represents  $-\text{N}^<$ , X represents  $-\text{CO}-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b = \text{OH}$ , Z represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$  and is substituted with OH,  $\text{Sp}_2$  represents a covalent bond, Y represents a substituted aryl (a substituted phenyl) and  $R_{21}$  represents a halogen (F) and  $R_{22}$  represents a halogen (F) (see page 974, compound 1, SCH 58235).

Claim 9 is drawn to a compound according to claim 7, wherein  $P = -\text{N}^<$ ,  $n = 1$  and  $X = -\text{CO}-$ ,  $-\text{CS}-$ ,  $-\text{CH}_2-$  or  $-\text{NH}-$ . Rosenblum et al. disclose applicant compound of formula IVa wherein P represents  $-\text{N}^<$ ,  $n = 1$ , and X represents  $-\text{CO}-$  (see page 974, compound 1, SCH 58235).

Claims 13 and 14 which are drawn to a pharmaceutical composition comprising a therapeutically effective amount of a compound of claim 1 with a pharmaceutically acceptable carrier and the intended use of the composition. Rosenblum et al. disclose applicant's composition or compound of formula I wherein P represents  $-\text{N}^<$ , X represents  $-\text{CO}-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b = \text{OH}$ , Z represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$  and is substituted with OH,  $\text{Sp}_2$  represents a covalent bond and Y represents a substituted aryl (a substituted phenyl) (see page 974, compound 1, SCH 58235; see also page 979, 1<sup>st</sup> col., 3<sup>rd</sup> paragraph). It should be noted that Rosenblum et al. composition or compound was prepared in the pharmaceutically acceptable carrier (ethanol) (see page 979, 1<sup>st</sup> col., 3<sup>rd</sup> paragraph). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for treating arteriosclerosis, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack*

114, USPQ 161. Claim 15 which is drawn to a kit comprising pharmaceutical composition according to claim 13 with intended use. Rosenblum et al. disclose applicant's composition or compound of formula I wherein P represents  $-\text{N}^{\leftarrow}$ , X represents  $-\text{CO}-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b = \text{OH}$ , Z represents a substituted aryl (a substituted phenyl),  $\text{Sp}_1$  represents a spacer unit  $-(\text{CH}_2)_p-$  wherein  $p = 3$  and is substituted with OH,  $\text{Sp}_2$  represents a covalent bond and Y represents a substituted aryl (a substituted phenyl) (see page 974, compound 1, SCH 58235). It should be noted that said kit does not add to the patentability of the composition or compound. It should be noted that it is well settled that "intended use" of a composition or product, e.g., for treating arteriosclerosis, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. In claim 16, applicant claims a method for the treatment or prevention of arteriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a compound according to claim 1. Rosembum et al. disclose applicant's method of reducing cholesterol comprising administering to a subject (hamster) a compound of formula I (compound 1, SCH 58235) wherein P represents  $-\text{N}^{\leftarrow}$ , X represents  $-\text{CO}-$ ,  $n = 1$ ,  $R_a = \text{H}$ ,  $R_b$  represents OH (see page 973, 2nd col., 1st paragraph).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

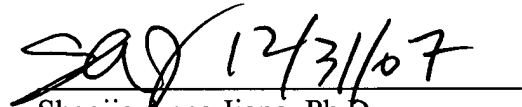
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reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

  
Shaojia Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1623

December 29, 2007.